

REMARKS

The attached substitute specification excluding the claims and abstract (clean form, 34 pages) is submitted in response to the Notice to File Corrected Application Papers mailed January 20, 2004. The Notice indicated that the specification as originally filed was not acceptable and could not be scanned or properly stored because pages 22 and 24 contained hand lettering. The Notice required a substitute specification in compliance with 37 C.F.R. 1.52, 1.121(b)(3), and 1.125.

37 C.F.R. 1.125(c) states:

A substitute specification submitted under this section must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record...[a]n accompanying clean version (without markings) must also be supplied....

However, Applicants have already filed three Preliminary Amendments which include amendments to the specification as originally filed. Consequently, the specification as originally filed, which includes the objectionable hand lettering, is no longer the immediate prior version of the specification of record.

In order to provide the Office a substitute specification that may be scanned and properly stored, Applicants have submitted the attached substitute specification excluding the claims and abstract in clean format, which does not include the objectionable hand lettering. The attached substitute specification incorporates the amendments to the specification made by the Preliminary Amendments filed on October 16, 2003, February 10, 2004 and February 26, 2004, but does not make any changes to the immediate prior version of the specification, i.e., include any additional amendments, other than removal of the objectionable handwriting. Applicants have also attached a copy of the specification as originally filed, with markings to show removal of the hand lettering, and a copy of each Preliminary Amendment that has been incorporated into the substitute specification (clean version, 34 pages). No new matter has been added by the enclosed substitute specification.

Applicants believe that these submissions are in compliance with the requirements of 37 C.F.R. 1.125, provide the Office with a substitute specification that may be scanned and properly stored, and will provide the Examiner with a clear record of the amendments made to the

specification to date. If Applicants' submissions are believed to be inappropriate or incomplete, please telephone the below-signed attorney.

Applicants also submit the attached replacement drawings for Figures 23 and 24 in response to the Notice to File Corrected Application Papers mailed January 30, 2004. The replacement drawing sheets correct problems identified in the original drawing sheets with respect to line quality, text legibility, and text height. Figures 23 and 24 are now in compliance with 37 C.F.R. 1.84 and 37 C.F.R. 1.121.

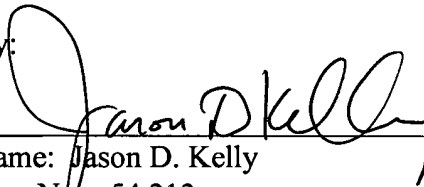
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

4-20-04

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By:



Name: Jason D. Kelly
Reg. No.: 54,213



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John T. Kilcoyne;
Ross Tsukashima;
George M. Johnson;
Christopher F. Klecher

Docket No.: 1065-012US04

Filed: Herewith

Anticipated Group Art
Unit: 3736

Title: IMPLANTABLE MONITORING PROBE

CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: ET691521795US

Date of Deposit: October 16, 2003

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, Alexandria, VA 22313-1450.

By:

Name: Shirley A. Betlach

PRELIMINARY AMENDMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please amend the specification by replacing the first paragraph in the application with the following amended paragraph:

This application is a divisional application of U.S. Application No. 09/544,373, filed April 6, 2000, which is a continuation-in-part of U.S. Application No. 09/287,617, filed April 7, 1999.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-32 (Canceled)

Claim 33 (Original): An implantable device for measuring at least one physiological parameter indicative of gastroesophageal reflux, the device comprising:

a casing adapted to be implanted and secured within the body of the patient in a location wherein the surrounding environment provides the at least one physiological parameter indicative of gastroesophageal reflux;

a sensor, positioned within the casing, the is adapted to measure the at least one physiological parameter indicative of gastroesophageal reflux;

a transmitter, positioned within the casing, wherein the transmitter is adapted to send a parameter signal indicative of the measured at least one physiological parameter to a receiver located outside of the body of the patient;

a power source, positioned within the casing, that provides power to the sensor and the transmitter;

a processor, positioned within the casing, that periodically induces the sensor to obtain the at least one physiological parameter and periodically induces the transmitter to transmit a parameter signal indicative of the at least one physiological parameter, wherein the processor enables the delivery of power from the power source to the sensor during a first time interval during each measurement cycle when the sensor is sensing the at least one physiological parameter and wherein the processor enables the delivery of power from the power source to the transmitter during a second time interval during each measurement cycle when the transmitter is transmitting the parameter signal so that consumption of power by the sensor and the transmitter is reduced during intervals of each cycle other than the first and second interval respectively.

Claim 34 (Original): The implantable device of Claim 33, wherein the sensor is comprised of a pH sensor that measures the pH of the fluid surrounding the casing when the casing is implanted in the patient's body.

Claim 35 (Original): The implantable device of claim 34, wherein the sensor is comprised of an ISFET transistor with an associated amplifier wherein the ISFET transistor is selectively activated in response to the pH of the fluid surrounding the casing such that the ISFET and the associated amplifier can provide a voltage signal to the microprocessor that is indicative of the pH of the surrounding fluid.

Claim 36 (Original): The implantable device of claim 34, wherein the sensor is comprised of an antimony electrode with an associated amplifier wherein the antimony electrode is selectively activated in response to the pH of the fluid surrounding the casing such that the antimony electrode and the associated amplifier can provide a voltage signal to the microprocessor that is indicative of the pH of the surrounding fluid.

Claim 37 (Original): The implantable device of Claim 33, wherein the transmitter is comprised of an RF transmitter that transmits a digital signal indicative of the physiological parameter indicative of gastroesophageal reflux.

Claim 38 (Original): The implantable device of Claim 33, wherein the processor initiates a measurement cycle wherein the sensor senses the physiological parameter and the transmitter transmits a parameter signal corresponding to the physiological parameter measured by the sensor approximately every 6 seconds.

Claim 39 (Original): The implantable device of Claim 38, wherein the processor provides power to the sensor only during the first interval and provides power to the transmitter only during the second interval of the cycle so as to reduce power consumption during each cycle.

Claim 40 (Original) The implantable device of Claim 39, wherein the first interval is approximately 20 ms in length and the second interval is approximately 60 ms in length.

Claim 41 (Original) The implantable device of Claim 33, further comprising a non-volatile memory accessible by the processor, wherein the processor is adapted so that calibration information can be stored in the non-volatile memory prior to implantation of the device into the patient.

Claim 42 (Original) The implantable device of Claim 41, wherein the parameter signals transmitted by the transmitter include the calibration data such that the receiver external to the patient receives a calibrated signal indicative of the physiological parameter indicative of gastroesophageal reflux.

Claim 43 (Original) A method of measuring a physiological parameter indicative of gastroesophageal reflux using an implanted sensor, the method comprising:

- (a) providing power to a sensor circuit for a first time interval so as to obtain a parameter measurement indicative of gastroesophageal reflux;
- (b) ceasing providing power to the sensor circuit following the first time interval;
- (c) providing power to a transmitter circuit during a second time interval, following the first time interval so that a parameter signal indicative of the parameter measurement obtained by the sensor circuit can be transmitted to a receiver located outside of the body of the patient; and
- (d) ceasing providing power to the transmitter circuit following the second time interval.

Claim 44 (Original) The method of Claim 43, wherein providing power to the sensor circuit comprises providing power to an ISFET transistor that is electrochemically activated by the pH of the fluid surrounding the implanted sensor and that produces a voltage signal that is proportionate to the pH of the fluid surrounding the implanted sensor.

Claim 45 (Original) The method of 44, wherein power is provided to the sensor for approximately 20 ms during the first time interval.

Amd dated October 16, 2003

Claim 46 (Original) The method of Claim 44, further comprising providing a digital signal representative of the physiological parameter measured by the sensor so that providing power to the transmitter circuit results in the digital signal being transmitted to the receiver located outside of the body of the patient.

Claim 47 (Original) The method of Claim 46, wherein providing power to the transmitter circuit during a second time interval comprises providing power to a RF transmitter.

Claim 48 (Original) The method of Claim 47, wherein power is provided to the transmitter for approximately 60 ms during the second time interval.

Claim 49 (Original) The method of Claim 43, wherein the acts (a) and (b) are periodically repeated every 6 seconds and steps (c) and (d) are periodically repeated every 12 seconds.

Claims 50-54 (Canceled)

Amd dated October 16, 2003

CONCLUSION

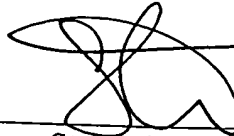
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

10-16-03

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By:



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Reg. No.: 36,275



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John T. Kilcoyne; Ross Tsukashima; George M. Johnson; Christopher F. Klecher	Anticipated Group Art Unit:	3736
Serial No.:	10/687,298	Docket No.:	1065-012US04
Filed:	October 16, 2003	Customer No.:	28863
Title:	IMPLANTABLE MONITORING PROBE		

PRELIMINARY AMENDMENT

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Amendments to the Drawings begin on page 8 of this paper and include both an attached replacement sheet and an annotated sheet showing changes.

Remarks begin on page 9 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace the first paragraph in the application with the following amended paragraph:

This application is a divisional application of U.S. Application No. 09/544,373, filed April 6, 2000, which is a continuation-in-part of U.S. Application No. 09/287,617, filed April 7, 1999. The entire content of each of these U.S. Applications is incorporated herein by reference.

Please replace the paragraph beginning at line 21 of page 22 with the following amended paragraph:

Intermediate tube 210 extends from a manifold 212 to the distal end 214. Manifold 212 may be provided with any of a variety of access ports, depending upon the desired functionality of the delivery catheter 138. In the illustrated embodiment, the manifold 212 is provided with a vacuum port 214 215. The vacuum port 214 215 is in communication with a central lumen (not illustrated) within the intermediate tube 210, which communicates with the cavity 124 in probe 18 when the probe is engaged in the docking structure 142. This enables application of vacuum to the vacuum port 214 215, to draw tissue within cavity 124 in the probe 18 as has been discussed.

Please replace the paragraph beginning at line 7 of page 24 with the following amended paragraph:

Fig. 16 illustrates the delivery catheter 138 in a position such that the probe 18 is in contact with the wall of the tissue structure 224. Vacuum has been applied to the vacuum port 214 215, which is in communication with the cavity 124 by way of intermediate tube 210 and lumen 130. In this manner, a portion of tissue 224 has been drawn within cavity 124.

AMENDMENTS TO THE CLAIMS

Please amend claims 33-37, 39, 40, and 42-49, and add new claims 55 and 56 as indicated below. This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-32 (Canceled)

Claim 33 (Currently Amended): An implantable device for measuring at least one physiological parameter indicative of gastroesophageal reflux, the device comprising:

a casing adapted to be implanted and secured within the body of ~~the~~ a patient in a location wherein the surrounding environment provides the at least one physiological parameter indicative of ~~gastroesophageal~~ gastroesophageal reflux;

a sensor, positioned within the casing, wherein the sensor is adapted to measure the at least one physiological parameter indicative of gastroesophageal reflux;

a transmitter, positioned within the casing, wherein the transmitter is adapted to send a parameter signal indicative of the measured at least one physiological parameter to a receiver located outside of the body of the patient;

a power source, positioned within the casing, that provides power to the sensor and the transmitter;

a processor, positioned within the casing, that periodically induces the sensor to obtain the at least one physiological parameter and periodically induces the transmitter to transmit a parameter signal indicative of the at least one physiological parameter, wherein the processor enables ~~the~~ delivery of power from the power source to the sensor during a first time interval during each measurement cycle when the sensor is sensing the at least one physiological parameter and wherein the processor enables ~~the~~ delivery of power from the power source to the transmitter during a second time interval during each measurement cycle when the transmitter is

transmitting the parameter signal so that consumption of power by the sensor and the transmitter is reduced during intervals of each cycle other than the first and second interval respectively.

Claim 34 (Currently Amended): The implantable device of Claim 33, wherein the sensor is comprised of a pH sensor that measures the a pH of the a fluid surrounding the casing when the casing is implanted in the patient's body.

Claim 35 (Currently Amended): The implantable device of eClaim 34, wherein the sensor is comprised of an ISFET transistor with an associated amplifier wherein the ISFET transistor is selectively activated in response to the pH of the fluid surrounding the casing such that the ISFET and the associated amplifier can provide a voltage signal to the microprocessor that is indicative of the pH of the surrounding fluid.

Claim 36 (Currently Amended): The implantable device of eClaim 34, wherein the sensor is comprised of an antimony electrode with an associated amplifier wherein the antimony electrode is selectively activated in response to the pH of the fluid surrounding the casing such that the antimony electrode and the associated amplifier can provide a voltage signal to the microprocessor that is indicative of the pH of the surrounding fluid.

Claim 37 (Currently Amended): The implantable device of Claim 33, wherein the transmitter is comprised of an RF transmitter that transmits a digital signal indicative of the physiological parameter that is indicative of gastroesophageal reflux.

Claim 38 (Original): The implantable device of Claim 33, wherein the processor initiates a measurement cycle wherein the sensor senses the physiological parameter and the transmitter transmits a parameter signal corresponding to the physiological parameter measured by the sensor approximately every 6 seconds.

Claim 39 (Currently Amended): The implantable device of Claim ~~38~~ 33, wherein the processor provides power to the sensor only during the first interval and provides power to the transmitter only during the second interval of the cycle so as to reduce power consumption during each cycle.

Claim 40 (Currently Amended) The implantable device of Claim ~~39~~ 33, wherein the first interval is approximately 20 ms in length and the second interval is approximately 60 ms in length.

Claim 41 (Original) The implantable device of Claim 33, further comprising a non-volatile memory accessible by the processor, wherein the processor is adapted so that calibration information can be stored in the non-volatile memory prior to implantation of the device into the patient.

Claim 42 (Currently Amended) The implantable device of Claim 41, wherein the parameter signals transmitted by the transmitter include the calibration data such that the receiver external to the patient receives a calibrated signal indicative of the physiological parameter that is indicative of gastroesophageal reflux.

Claim 43 (Currently Amended) A method of measuring a physiological parameter indicative of gastroesophageal reflux using an implanted sensor, the method comprising:

- (a) providing power to a sensor circuit for a first time interval so as to obtain a parameter measurement indicative of gastroesophageal reflux;
- (b) ceasing providing power to the sensor circuit following the first time interval;
- (c) providing power to a transmitter circuit during a second time interval, following the first time ~~interval~~ interval, so that a parameter signal indicative of the parameter measurement obtained by the sensor circuit can be transmitted to a receiver located outside of the body of the patient; and
- (d) ceasing providing power to the transmitter circuit following the second time interval.

Claim 44 (Currently Amended) The method of Claim 43, wherein providing power to the sensor circuit comprises providing power to an ISFET transistor that is electrochemically activated by ~~the~~a pH of ~~the~~a fluid surrounding the implanted sensor and that produces a voltage signal that is proportionate to the pH of the fluid surrounding the implanted sensor.

Claim 45 (Currently Amended) The method of ~~44~~43, wherein power is provided to the sensor for approximately 20 ms during the first time interval.

Claim 46 (Currently Amended) The method of Claim ~~44~~43, further comprising providing a digital signal representative of the physiological parameter measured by the sensor so that providing power to the transmitter circuit results in the digital signal being transmitted to the receiver located outside of the body of the patient.

Claim 47 (Currently Amended) The method of Claim ~~46~~43, wherein providing power to the transmitter circuit during a second time interval comprises providing power to a RF transmitter.

Claim 48 (Currently Amended) The method of Claim ~~47~~43, wherein power is provided to the transmitter for approximately 60 ms during the second time interval.

Claim 49 (Currently Amended) The method of Claim 43, wherein the acts (a) and (b) are periodically repeated every 6 seconds and ~~steps~~acts (c) and (d) are periodically repeated every 12 seconds.

Claims 50-54 (Canceled)

Claim 55 (New): The implantable device of Claim 33, wherein the casing is adapted to be implanted and secured within the esophagus of the patient.

Amd dated February 10, 2004

Claim 56 (New): The method of Claim 43, wherein providing power to the sensor circuit comprises providing power to an antimony electrode with an associated amplifier, the antimony electrode and the associated amplifier electrochemically activated by a pH of a fluid surrounding the implanted sensor to produce a voltage signal that is proportionate to the pH of the fluid surrounding the implanted sensor.

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to FIGS. 13 and 14. The sheet, which includes FIGS. 13 and 14, replaces the original sheet including FIGS. 13 and 14. The attached sheet of drawings adds reference numerals to FIGS. 13 and 14 that are mentioned in the specification, namely reference numerals 168, 172, 184, 188 and 190. The attached sheet of drawings makes the same changes to FIGS. 13 and 14 of the present application as made to FIGS. 13 and 14 during prosecution of the parent application, Application Serial No. 09/544,373.

Attachment: Replacement Sheet

Annotated Sheet Showing Changes

REMARKS

The Specification and Figures have been amended to correct minor editorial problems, which were previously discovered and corrected by amendment during prosecution of the parent application, Application Serial No. 09/544,373. Entry of these amendments and the above-indicated amendments to the claims prior to examination is courteously solicited.

Amd dated February 10, 2004

CONCLUSION

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

February 10, 2004
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By:

Jason D Kelly
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John T. Kilcoyne; Ross Tsukashima; George M. Johnson; Christopher F. Klecher	Anticipated Group Art Unit:	3736
Serial No.:	10/687,298	Docket No.:	1065-012US04
Filed:	October 16, 2003	Customer No.:	28863
Title:	IMPLANTABLE MONITORING PROBE		

PRELIMINARY AMENDMENT

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Amendments to the Specification begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace the first paragraph in the application with the following amended paragraph:

This application is a divisional application of U.S. Application No. 09/544,373, filed April 6, 2000, now issued as U.S. Patent No. 6,689,056, which is a continuation-in-part of U.S. Application No. 09/287,617, filed April 7, 1999, now issued as U.S. Patent No. 6,285,897. The entire content of each of these U.S. Applications is incorporated herein by reference.

REMARKS

The amendments made to the specification serve to update priority information only.
Applicants respectfully submit that no new matter has been added by this Amendment.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

February 26, 2004
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By:

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